

REMARKS

The applicant respectfully requests reconsideration of claims 1-3, 5-8, 14-15, 17, 25, and 52-75, and consideration of new claims 76-93. Previously withdrawn claims 9, 11-13, 16, 18-24 and 31-51 are cancelled in this amendment.

The applicant notes with appreciation the withdrawal of all rejections made in the previous (August 12, 2004) action, and the present indication that claims 6 and 58 incorporate allowable subject matter. The following comments are directed to the issues raised in the present action.

A. Claims 1-3, 8, 14-15, 17, 25, 52-56, 63-65 and 68-75 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by U.S. Patent No. 5,449,373 (Pinchasik et al.).

The Pinchasik patent discloses an articulated stent composed of rigid segments 102 joined to each other by connectors 110 comprised of links 112. In another version (Figures 3A-3C), the rigid segments are joined by connectors 124 including links 126. Both versions are formed of plastically deformable materials such as stainless steel 316L, gold, and tantalum (column 4, lines 1-5). Both versions require inflation of a balloon for their radial expansion at the treatment site (column 4, lines 8-14, lines 36-43). Connectors 110 are said to be “flexed in any direction and to provide continuous and uniform support to both straight and curved portions of a body conduit” (column 3, lines 40-43). These stents are said to eliminate “a number of disadvantages” of prior art self-expandable articulated intravascular stents, both during delivery and when implanted, such as a more complicated delivery due to the need for angular orientation, and gaps between segments that induce “non-uniform and therefore undesirable stresses” on a blood vessel (column 1, lines 27-62).

The prosthesis defined in claim 1 is not taught by Pinchasik, for several reasons. First, Pinchasik fails to teach a tubular structure including at least one flexible strand. As seen most clearly in Figures 2A, 2B, 3A and 3B, the Pinchasik stent has a structure formed by a cutting, stamping or otherwise selectively removing material from a sheet of the stent material. Thus, there are no strands of any sort. Moreover, assuming arguendo that the Pinchasik stents are composed of strands, such “strands” are not flexible as provided in claim 1. As noted above, the Pinchasik stent is fabricated from stainless steel 316L, gold, or tantalum, which form structures

that are plastically deformable. Thus, any “strand” taught by Pinchasik would be plastically deformable.

Second, Pinchasik fails to teach first and second tubular segments having nominal diameters when in a relaxed state and radially compressible against an elastic restoring force, as provided in claim 1. An elastic restoring force is developed in elastically deformable tubular structures when they are compressed radially from their relaxed states. Once the compressive force is removed, the elastic restoring force tends to return such tubular structure to its nominal diameter.

In contrast, when the plastically deformable stent of Pinchasik is radially compressed, it simply retains the reduced diameter. No elastic restoring force is developed.

Further, Pinchasik fails to teach a tubular structure with segments having first and second radial force levels when the tubular structure is radially compressed to a predetermined diameter. As noted in the present specification, the stent radially self-expands into engagement with the tissue wall before reaching its free state diameter. Thus, the stent retains an internal elastic restoring force which is exerted radially outwardly against the surrounding tissue. This force not only maintains lumen patency, but also tends to prevent stent migration. See the present specification at page 10, lines 1-7.

In contrast, although the Pinchasik stent provides support to maintain lumen patency, it does not develop a radially outward force when radially compressed to a predetermined diameter, but instead, simply remains at the diameter to which it has been compressed.

It is noted that Pinchasik refers to radially self-expanding stents, but only in a context of criticism and disapproval, as in Figure 1 showing a prior art self-expandable stent, the text describing Figure 1, and other text favorably comparing Pinchasik stents with self-expandable stents, for example “delivery . . . considerably simpler” as indicated in column 4 at lines 21-25.

Finally, Pinchasik fails to teach that the first tubular segments have higher axial stiffness levels. On page 2 of the present action, Pinchasik’s segments 102 are relied upon as showing the first segments. Then, it is argued that Pinchasik’s connectors 110/124, referred to as second segments (112), are “capable of applying more force in an axial direction” than rigid segments 102. This assertion runs counter to the feature in claim 1 that the first axial stiffness

levels are higher than the second axial stiffness levels, thus to further demonstrate the lack of anticipation.

Accordingly, the Pinchasik patent fails to anticipate the prosthesis defined in claim 1.

Claims 2, 3, 8, 14, 15 and 17 depend on claim 1, and are patentable for the reasons given in support of claim 1.

Claim 8 is patentable, further, for the failure of Pinchasik to teach a prosthesis in which the second radial force levels (of the second tubular segments) are higher than the first radial force levels of the first tubular segments. The segments having higher axial stiffness levels have lower radial force levels. With reference to claim 1, the radial force levels are present when the tubular structure is radially compressed against an elastic restoring force to the predetermined diameter.

As previously noted, the Pinchasik stents are plastically deformable. They exert no radial force in response to radial compression. Secondly, to the extent that the support function of the Pinchasik stent might arguendo be likened to the claimed radial force levels, there is no teaching that connectors 110 and 124 provide more support than rigid segments 102. Pinchasik actually refutes this proposition, teaching that the stent provides continuous and uniform support over straight and curved portions. See Pinchasik at column 1, lines 66-68, and at column 4, lines 28-35.

Claim 25 is drawn to a prosthesis including a tubular wall incorporating a plurality of first tubular wall segments and a plurality of second tubular wall segments in an alternating sequence. The wall segments have nominal diameters when in a relaxed state and are radially compressible against an elastic restoring force to a predetermined diameter. The first and second wall segments have respective axial stiffness levels when radially compressed to the predetermined diameter. The first tubular wall segments have relatively high first axial stiffness levels, and the second tubular wall segments have second axial stiffness levels lower than the first axial stiffness levels. As a result, the second tubular wall segments are adapted to more readily conform to body lumen curvature.

As noted above, the plastically deformable stents taught in Pinchasik are not radially compressible against an elastic restoring force. Radial compression of a plastically deformable

stent generates no elastic restoring force. Further, the above-referenced argument that the axial force of Pinchasik's connectors 110/124 is higher than that of Pinchasik's rigid segments 102 (Action, page 2), contradicts the claimed feature that the second axial stiffness levels are lower than the first axial stiffness levels.

Accordingly, claim 25 is patentable for the reasons given in support of claim 1.

Claims 52-56, 63-65, and 68-75 depend on claim 25 and are allowable for the reasons given in support of claim 25.

Claims 54, 55, 70 and 71 are patentable, further, for the failure of Pinchasik to teach first and second tubular wall segments having respective first and second radial force levels when radially compressed to the predetermined diameter. The Pinchasik structures provide support, but do not exert any radially outward force in response to radial compression. Also, as previously noted, Pinchasik teaches continuous and uniform support along its segments and connectors.

Claim 56 is patentable, further, for the failure of Pinchasik to teach a tubular wall composed of at least one flexible strand. The Pinchasik stents are not composed of strands, and the stent material is not flexible.

Claim 63 is patentable, further, for the failure of Pinchasik to teach filaments, and different numbers of filaments along first and second tubular wall segments. The Pinchasik segments and connectors do not incorporate filaments, the comments in the present action to the contrary (page 2) notwithstanding.

Claims 64 and 65 are patentable, further, for the failure of Pinchasik to teach a tubular wall including first and second different types of filaments. The context of the applicant's teaching as to different "types" of filaments is clear from claim 65, and clear from the specification. Different shapes are not different types.

Claim 68 is patentable, further, for the failure of Pinchasik to teach sets of flexible filaments spanning the tubular structure length, and other such sets extending only along the first tubular wall segments.

Claim 69 is patentable, further, for the failure of Pinchasik to teach a strand comprising a cable having at least two filaments.

B. Claims 1, 5, 7, 57, and 59-62 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,064,435 (Porter).

Porter discloses a variety of self-expanding prostheses, each having a stable axial length. The action relies on the version shown in Figure 6, which includes slidably connected proximal and distal stent segments 54 and 56. The segments overlap each other along a medial region 58. At the opposite ends of the stent, reinforcing strands are added to form proximal and distal reinforced end regions 64 and 66.

In the course of this rejection, it is contended in the present action (page 3) that reinforced end regions 64 and 66 along with medial region 58 provide “stiffer” first sections, while segments 54 and 56 (apparently the portions that are not reinforced) constitute the claimed second sections.

This assertion is respectfully traversed, mainly because the Porter stent does not teach the claimed alternating arrangement of first and second tubular segments. The action proposes that Porter’s medial section 58 is stiffer because it is formed of overlapped mesh (Action, page 3). Claim 1, however, provides that first axial stiffness levels of the first segments are higher than second axial stiffness levels of the second tubular segments.

Porter’s sections 54 and 56 are slidably connected. The advantage of the Porter prostheses, including that shown in Figure 6, is that the prosthesis length remains substantially the same during radial self-expansion because the different sections slide relative to one another. Therefore, the axial stiffness of proffered “segment 58” is virtually zero. Even allowing for friction to provide some axial stiffness along the slidable connection, this “segment 58 stiffness level” is considerably lower than the axial stiffness levels of segments 54 and 56. Otherwise, the stent fails to maintain its length as it radially expands.

In short, medial region 58 of Porter is not a discrete tubular segment, but instead is a region where two discrete tubular segments overlap one another in a sliding engagement. Accordingly, the Porter patent fails to anticipate the prosthesis of claim 1.

Claims 5 and 7 depend on claim 1, and are patentable for the reasons given in support of claim 1.

Claim 25 is patentable for the reasons given in support of claim 1, because it likewise defines an arrangement of alternating first and second tubular wall segments having respective first and second axial stiffness levels, with the first levels being higher than the second.

Claims 57 and 59-62 depend on claim 25 and are patentable for the reasons given in support of claim 25.

Claim 60 is patentable, further, in that Porter does not teach a stent in which second tubular wall segments have larger nominal diameters than first tubular wall segments. Contrary to the implication of certain comments specifically directed to claim 60 (Action, page 3), reinforcing strands do not inherently increase the stent thickness, nor do they inherently change the stent diameter.

C. Claims 66 and 67 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Pinchasik in view of U.S. Patent No. 6,045,568 (Igaki, et al.).

Igaki discloses stents formed of bioresorbable polymer fiber.

In connection with this rejection, it is asserted in the present action (page 4) that it would have been obvious “to form Pinchasik’s whole stent out of bioabsorbable material so that it will dissolve within a few months of implantation.”

Claim 66 further defines the prosthesis of claim 65 in that the second of two filament types is bioabsorbable. The first filament type, also present in the tubular wall, is either metallic or non-metallic and biostable.

Accordingly, assuming arguendo that forming Pinchasik’s “whole stent” out of bioabsorbable material would have been obvious, such does not teach the prosthesis defined in claim 66, which calls for two filament types, only one of which is bioabsorbable. Further, Igaki - like Pinchasik - teaches plastically deformable, balloon expandable prostheses, and thus teaches nothing to compensate for the shortcomings of Pinchasik discussed above in connection with claims 1 and 25.

Claim 67 further defines the prosthesis of claim 56 in that the at least one flexible strand includes a plurality of biostable filaments and a plurality of bioabsorbable filaments. Again, the claimed combination of filament types is not met by forming Pinchasik’s “whole stent” out of

bioabsorbable material. Again, there is no teaching in either reference of an elastically deformable tubular wall formed of flexible filaments.

Accordingly, claims 66 and 67 are patentable over the Pinchasik/Igaki combination.

New claim 76 incorporates limitations of claims 1, 5 and 6, and accordingly is equivalent to claim 6 rewritten in independent form. Claim 76, and claims 77-83 which depend on claim 76, are believed to be in condition for allowance.

New claim 84 incorporates limitations of claims 25, 56, 57 and 58, and thus is equivalent to claim 58 written in independent form. Claim 84, along with claims 85-93 which depend on claim 84, are believed to be in condition for allowance.

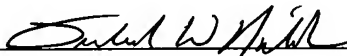
In summary, it is submitted that claims 1-3, 5-8, 14-15, 17, 25, and 52-93 define subject matter patentable over the prior art of record. The proposed amendment consists of new claims drawn to subject matter already claimed, and thus does not touch upon the merits of the application. The new claims would not require any further consideration or searching on the part of the examiner. The amendment places the claims in condition for allowance.

Accordingly, the applicant requests entry of the foregoing amendment, and allowance of the claims identified immediately above.

Respectfully submitted,

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Dated: June 20, 2005

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CERTIFICATE OF MAILING

Pursuant to 37 CFR 1.8, I hereby certify that this Amendment Pursuant to 37 C.F.R. 1.116 in Application Serial No. 10/038,640 is being deposited with the U.S. Postal Service by first class mail, postage prepaid, in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date of deposit indicated below.

Date of Deposit: June 20, 2005



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